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09/988,954	11/21/2001	Peter M. Bonutti	BON-1721-11	9219

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,954

Applicant(s)

BONUTTI, PETER M.

Examiner

Paul B. Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 62-102 is/are pending in the application.
- 4a) Of the above claim(s) 64-66, 68, 72-75, 77-95 and 97-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62, 63, 67, 69-71, 76 and 96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 5 6) ☐ Other: _____

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Election/Restrictions

Claims 72-75, 77-80, 82, 84-87, 90, 93, 95, and 97-99 were stated as be^{not} directed to the elected invention and species, and thus they were withdrawn from further consideration pursuant to 37 CFR 1.142(b). However, upon review of the election and the claims of record, it was determined that claims 64-66, 68, 81, 83, 88, 89, 91, 92, 94, and 100-102 ^{should also have been} were withdrawn as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6 filed December 5, 2002. The additional claims were withdrawn because they included limitations to body tissue not biodegradable material as elected. Since "body tissue" is a generic term encompassing only Species "1" (tendon tissue) and Species "3" (bone tissue), the additional claims were considered to be drawn to non-elected species. It is noted that the elected species of biodegradable material is not generic to body tissue as claimed because biodegradable material is clearly disclosed in the specification as pertaining to the retainer materials and is not disclosed as encompassing the tissue components in any manner.

Applicant's election with traverse of Group II, Species (e), Species 4, and Species I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that (1) a significant number of claims are generic and (2) there is no serious burden to search and examine all claims. This is not found persuasive because (1) at least 18 claims are not generic to the elected species according the Applicant's own election; note that claims 64-66, 68, 81, 83, 88, 89, 91, 92, 94, and 100-102 were stated by Applicant as being directed to other species. Furthermore, a

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significant number of generic claims does not reduce the burden or make the species indistinct as Applicant argues. With regard to traversal (2), the Examiner asserts that there is a serious burden because the species are independent with each having a different classification; e.g. species b (screws) is classified in class 606, subclass 65, species g (acetabular cup) is classified in class 623, subclass 22.21, and species j (joint replacement) is classified in class 623, subclass 18.11. Each additional species would require at least another subclass to be searched. There are 20 species in all, and therefore, approximately an additional 20 subclasses^{es} would have to be searched if all the claims were examined. Then the additional claims (34 claims) and species would have to be examined for their patentability. However, in order to reduce this burden, Applicant could admit on record that all the species are obvious variants of each other.

Applicant requested that the Examiner reconsider the restriction requirement. Upon review, the Examiner determined that the Applicant's arguments were unpersuasive and that the restriction requirement was proper.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The abstract of the disclosure is objected to because it is not directed to the presently elected invention. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive of the presently elected invention and species. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities:

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The continuing data on page 1 of the specification is not updated with the current status of each parent application. Furthermore, the continuing data uses the words "copending" even when that is no longer true for most of the applications listed.

On page 20, line 13, the word "pat" appears to be a misspelling for ---part---

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 62, 63, 71, and 76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 70, and 74 of copending Application No. 10/033,515. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are broader in scope such that they are read

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on by the copending claims. For this reason, the present claims are considered to be clearly obvious in view of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 62, 63, 67, 69-71, 76, and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey (US 4,890,612). Kensey discloses a method of positioning a surgical implant, a leasing member in this case, in a patient's body to seal a puncture; see the abstract and Figure 6. The sealing device (20) includes a sealing member (106), which expands by absorbing body fluids such as blood; see column 6, lines 24-51, column 7, lines 6-10 and lines 46-54 and claim 1. The entire device (20) of Kensey can be biodegradable; see column 6, lines 24-51.

With regard to claim 67, the sealing plug (106) made of collagen or gelatin is inherently hydrophilic since it absorbs aqueous fluids such as blood.

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Claims 62, 63, 67, 69, 70, 71, 76, and 96 are rejected under 35 U.S.C. 102(e) as being anticipated by Draenert (US 5,084,050). Draenert discloses a bioabsorbable fastener (bone screw dowel) which absorbs body fluids to swell or expand and hold the fastener and bone screw in the body; see Figure 1 and column 2, line 53 to column 5, line 60.

With regard to claim 96, the first and second components as claimed are met by the material components of the absorbable surgical implant material of Draenert; see column 4, line 55 to column 5, line 11.

Conclusion

The prior art made of record by Applicant's IDS and not relied upon is considered pertinent to applicant's disclosure.

In treatment of "thoracolumbar fractures", resected bone (i.e. bone tissue) is packed into the Brantigan (US 5,192,327) implant (see column 2, lines 44-51). The Brantigan implant can be made of PEEK (i.e. polyetherether ketone) (see column 3, lines 9-18) so it is inherently a material which expands when exposed to body fluid as claimed; see page 31, line 26 to page 32, line 3 of the present specification. Since the same material PEEK is used by Brantigan as used in the present invention to expand with fluid contact, it inherently has this property. Since Brantigan's device is implanted in the vertebral column to allow bone fusion, it inherently is in contact with body fluids. For this reason, Brantigan also would anticipate most of the elected claims.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that

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other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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